510(k) SUMMARY OF SAFETY AND EFFECTIVENESS: K110508

JUN - 3 2011

Submitter

Company:.....3M ESPE AG

Street:.....ESPE Platz

ZIP-Code, City:.....D-82229 Seefeld

Federal State: .....Bavaria

Country: .....Germany

Establishment Registration Number 9611385

Official Correspondent: .....Dr. Desi W. Soegiarto,

.....Regulatory Affairs Specialist

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Date:.....May 04, 2011

Name of Device

Proprietary Name:.....Suglue-10

Classification Name:.....Dental cement other than zinc oxide-eugenol

Common Name: .....Adhesive resin cement

Predicate Devices

Malta by 3M ESPE, Germany K100756

Panavia F 2.0 by Kuraray Medical Inc., Japan K032455

Nexus 3 by Kerr Corporation, U.S.A., ...K062519

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Description for the Premarket Notification

Suglue-10 is classified as a Dental cement other than zinc oxide-eugenol (21 C.F.R. §872.3275 [b]) because it is a device composed of various materials other than zinc oxide-eugenol.

Suglue-10, manufactured by 3M ESPE, is a dual-curing resin cement supplied in an automix syringe. It is intended to be used for the adhesive cementation of indirect restorations and will be available in various shades.

Suglue-10 is intended to be used in combination with an adhesive, e.g. Adhesive EXL 759 (by 3M ESPE). The Adhesive EXL 759 can be used either as a "Total Etch" or "Self-Etch" procedure. The additional etching of the tooth structure increases the adhesive strength of the adhesive even further.

Suglue-10 contains bi-functional (meth)acrylate. The proportion of inorganic fillers is about 43% by volume; the grain size (D 90%) is about 13 µm. The mixing ratio, based on volume, is 1 part base paste : 1 part catalyst.

Predicate devices to which Suglue-10 has been compared are Malta by 3M ESPE, Germany (K100756), Panavia F 2.0 by Kuraray Medical Inc., Japan (K032455) and Nexus 3 by Kerr Corporation, U.S.A. (K062519).

Technological Characteristics

As its predicate devices, Suglue-10 is a dual-curing, resin-based cement. Suglue-10 cement is based on the Malta material (K100756, by 3M ESPE, Germany).

As Suglue-10 is designed to compete with the latest state of the art adhesive resin cements, its in vitro performance was compared to the newer system Nexus 3 and the still widely used Panavia F2.0.

The intended use of Suglue-10 is comparable to the area of the intended use of the predicate devices of Suglue-10.

In this 510(k) premarket notification Suglue-10 has been compared to its predicate devices with regard to chemical composition, performance data and indications for use.

Biocompatibility testing was carried out.

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Performance Data

The following table shows the performance data of Suglue-10 and its predicate device Malta (K100756):

				Suglue-10	Malta
		Method	Limit	Results	
Film thickness		ISO 4049	< 50 µm	10 ± 2	13 ± 1
Working time		ISO 4049	> 60 sec	pass	pass
Setting time		ISO 4049	< 10 min	03:30	03:30
Radiopacity		ISO 4049	> 1.0 mm	2.3	1.8
Flexural strength	dark cured	ISO 4049	> 50 MPa	77 ± 5	84 ± 12
	light cured		> 50 MPa	111 ± 7	111 ± 16
Compressive strength	dark cured	ISO 9917	na [MPa]	278 ± 9	263 ± 9
	light cured		na [MPa]	286 ± 36	256 ± 36
Surface hardness	dark cured	ISO 2039-1	na [MPa]	187 ± 12	190 ± 20
	light cured		na [MPa]	217 ± 83	212 ± 30

In summary, it can be concluded that Suglue-10 is as safe and effective as the predicate devices: Malta by 3M ESPE, Germany (K100756), Panavia F 2.0 by Kuraray Medical Inc., Japan (K032455), and Nexus 3 by Kerr Corporation, U.S.A. (K062519).

Indications for Use:

- Final cementing of all-ceramic, composite, or metal inlays, onlays, crowns and bridges; 2-3-unit Maryland bridges and 3-unit inlay/onlay bridges (excluded for patients with bruxism or periodontitis)
- Final cementing of posts and screws
- Final cementation of all-ceramic, or composite veneers
- Final cementation of all-ceramic, composite, or metal restorations on implant abutments

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Conclusion of Substantial Equivalence

The comparison for chemistry, performance data and indications for use shows that Suglue-10 is substantially equivalent to the predicate devices: Malta by 3M ESPE, Germany (K100756), Panavia F 2.0 by Kuraray Medical Inc., Japan (K032455) and Nexus 3 by Kerr Corporation, U.S.A. (K062519).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Desi W. Soegiarto
3M ESPE AG
ESPE Platz
Seefeld, Bavaria
Germany D-82229

Re: K110508
Trade/Device Name: Suglue-10
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: May16, 2011
Received: May 23, 2011

JUN - 3 2011

Dear Ms. Soegiarto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110508

Indications for Use

510(k) Number (if known):

Device Name: Suglue-10

Indications For Use:

- Final cementing of all-ceramic, composite, or metal inlays, onlays, crowns and bridges; 2-3-unit Maryland bridges and 3-unit inlay/onlay bridges (excluded for patients with bruxism or periodontitis)
- Final cementing of posts and screws
- Final cementation of all-ceramic, or composite veneers
- Final cementation of all-ceramic, composite, or metal restorations on implant abutments

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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